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REMARKS

Status of Claims

Claims 5-12 and 27-31 are still pending. (see next page for continuation of "Remarks" section).

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Prosecution History Highlights

As it is presumed that the examiner is aware of the prosecution history of this application, the table below is presented by the applicants' representative for the benefit of the applicants, the examiner's SPE and the administrative patent judges of the Board of Patent Appeals and Interferences

Date	Paper #	Action	Result
12/20/2001	6	First office action which included prior art rejections using <i>abstract</i> of PI 9303217 (referred to as BR 9303217) and Znaiden et al. (U.S. Patent 5,523,090) 112, 1 st paragraph rejection made over "increasing the synthesis rate of ceramides of human skin" Examiner Alysia Berman Signer: Diana Dudash	Applicants filed response which included addition limitations to independent claim 5.
10/9/2002	11	Premature final rejection wherein rejection based on <i>full document</i> of PI 9303217 is made and <i>rejection based on Znaiden et al. is withdrawn</i> . 112, 1 st paragraph rejection maintained. Examiner Alysia Berman Signer: Russell Travers	Applicants <i>petitioned finality of rejection</i> (Paper No. 12)
1/3/2003	13	Petition to withdraw finality is GRANTED Director: John Doll	Applicants file response which included additional limitations to independent claim 5.
3/18/2003	15	Final rejection based on full document of <i>PI 9303217 is withdrawn</i> and rejection based on <i>Znaiden et al. is reinstated</i> . (Recycled rejection #1) 112, 1 st paragraph rejection maintained. Examiner Lauren Wells Signer: Sreeni Padmanabhan	In order to advance prosecution, <i>second petition for premature final rejection is waived</i> by applicants and rejection based on Znaiden et al. is argued.
5/7/2003	17	Advisory Action is mailed affirming the rejection made over Znaiden et al. 112, 1 st paragraph rejection <i>is withdrawn</i> . Examiner Lauren Wells Signer: Sreeni Padmanabhan	Notice of Appeal is filed and Appeal Brief is filed.
9/26/2003	20	Examiner telephones applicants to offer suggested amendment to place application in condition for allowance	Applicants' representative declines the offer.

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		which had not previously been offered. (Summarized in Interview Summary Form which is part of Paper No. 20)	
		Examiner Lauren Wells Signer: Sreeni Padmanabhan	
10/3/2003	20	Prosecution on the merits is reopened and the rejection based <i>Znaiden et al.</i> is <i>withdrawn</i> and a rejection based on the full document of <i>PI 9303217</i> is <i>reinstated</i> . (Recycled rejection #2) 112, 1 st paragraph rejection is <i>reinstated</i> . (Recycled rejection #3) Examiner Lauren Wells Signer: Sreeni Padmanabhan	This response

35 U.S.C. 112, first paragraph rejection

The examiner has apparently just repeated her rejection from the final rejection with no explanation as to why the applicants' amendment after final response is now no longer considered to be persuasive as this rejection was withdrawn as part of the Advisory Action of 7 May 2003. As such, the applicants' request that the examiner consider and address the applicants' response on this matter from the Amendment Under 37 CFR § 1.116 filed on 1 May 2003 which is reproduced below:

"However, in the applicants' previous response (dated 9 January 2003), attention was directed towards page 5, fourth paragraph of the specification for support of the limitation represented by claim 29. This paragraph also contained the phrase "increase the synthesis rate of ceramides in human skin in general."

Moreover, the examiner acknowledged that sphingolipids are lipids containing sphingosine. Referring to page 7, first paragraph of the applicants' previous response, it was indicated that ceramides are examples of sphingolipids. A dictionary definition of "ceramide" from Dorland's Pocket Medical Dictionary: any of a group of naturally occurring sphingolipids in which the NH₂ group of sphingosine is acylated with a fatty acyl CoA derivative to form an N-acylsphingosine. Again, referring to the relatively low threshold required to meet the written description requirement (and that, while certainly helpful, there is no requirement under 35 U.S.C. 112 for *ipsis verbis* support for the claimed subject matter in the specification), it is unclear what is the basis for the examiner's holding of new matter.

35 U.S.C. 103(a) rejection

Claims 5-12 and 27-31 were rejected by the examiner over Kurose et al. (PI 9303217). This rejection is objected primarily on two grounds which include:

- (1) On the merits: No explanation has been given as to why this rejection has now been resurrected when it had been previously addressed by the applicants and withdrawn by the examiner. As such, the applicants have essentially

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r submitted the applicants' response of 9 January 2003 with minor modifications.

- (2) Examiner's indecision is *prima facie* evidence that there is no holding of *prima facie* obviousness.

(1) On the merits

It is presumed that the examiner was basing her rejection on the English language translation of the Kurose reference which was obtained by an earlier examiner and a copy of which was presented to the applicants. If so, the examiner's characterization of the teachings of the Kurose reference is incorrect on at least two levels and is probably the reason why this reference was earlier withdrawn from consideration.

First, Kurose does not teach that "catechins provide various benefits which as skin-softening, skin moisturizing and emolliency". The only specific recitation of effect which is attributed to catechins alone is anti-oxidant activity (see page 4). The statement made by the examiner appears to refer to the extract as a whole, i.e. there is no attribution of the properties stated by the examiner for strictly catechins.

Second, Kurose does not teach "...wherein catechins comprise 20.3% of the extract or 0.02-0.2% of the composition." The examiner's calculation of the 0.02-0.2% range is presumably based on combining the teaching on page 8 with the MTE-1 composition of page 3. However, a more careful reading of the MTE-1 composition reveals that the 20.3% range refers to "...secondarily of substances of catechin groups, *other flavanoids, polymerized catechins and other low molecular weight polyphenols (20.3% of total)*". There is no indication how much catechins are actually in this 20.3% range and the examiner has not established any factual basis for presuming the ranges claimed by the applicants *for their method of use* is taught or suggested by Kurose.

Consideration of the claimed invention and the prior art "as a whole" are two of the four tenets of patent law which *must* be adhered to when applying 35 U.S.C. § 103 (see 2100-116, Rev. 1, Feb. 2003) and this clearly was not done when reviewing the Kurose reference to formulate the rejection.

With regard to the examiner's recitation of *In re Pearson* and *In re Tuominen*, even if the compositions could be proved to be anticipated or obvious, the examiner is reminded that MPEP 2144.04 states that "...if the facts in a prior legal decision are sufficiently similar to those in an application under examination, the examiner may use the rationale used by the court." However, for both of the decisions cited by the examiner the issue at hand was a comparison of the claimed composition with the prior art compositions, this is not the case here; all of the claims are directed toward method of using claims. (see relevant headnotes from each decision)

In re Pearson, 181 USPQ 641 (CCPA 1974).

PATENTS

[3] Patentability -- New use or function -- **Composition of matter (§ 51.555)**

Terms merely setting forth intended use for, or a property inherent in, an otherwise old composition do not differentiate claimed composition from those known to prior art; court does not mean to imply that terms which recite intended use or a property of a composition can never be used to distinguish a new from an old composition; however, assuming their compliance with definiteness requirement of second paragraph of 35 U.S.C. 112, such terms must define, indirectly at least, some characteristic not found in old composition.

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In re Tuominen, 213 USPQ 89 (CCPA 1982)

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[2] Patentability -- **Composition of matter** (§ 51.30)

Patentability -- New use or function -- In general (§ 51.551)

Difference in use cannot render claimed composition novel.

The idea that an invention based on the discovery of an unobvious use of an old composition must be claimed in a method or process claims, not product claims has been long established in the courts. see *In re Moreton*, 288 F.2d 708, 129 USPQ 227 (CCPA 1961), *In re Heck*, 245 F.2d 246, 114 USPQ 181 (CCPA 1957), *Clinical Products Ltd. v. Brenner, Comr. Pats.*, 255 F.Supp. 151, 149 USPQ 475 (DCDC 1966).

(2) Examiner's indecision is *prima facie* evidence that there is no holding of *prima facie* obviousness

The last four communications from the PTO were the result of examination by Examiner Lauren Wells and signed by SPE Sreeni Padmanabhan. In addition, the claims have remained the same from the time Examiner Wells wrote her first communication up till the date of this response. Therefore, such the reversal of positions cannot be explained away by changes in examiners (which is normally not a valid excuse in any event as described above) or by changing subject matter within the claims.

MPEP 2142 states that when making a determination of obviousness, the standard applied is whether there is a "preponderance of evidence" for obviousness:

"The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness [page 2100-123]...The ultimate determination of patentability is based on the entire record, by a preponderance of evidence, with due consideration to the persuasiveness of any arguments and any secondary evidence. *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). The legal standard of "a preponderance of evidence" requires the evidence to be more convincing than the evidence which is offered in opposition to it.

With regard to the rejections under 35 U.S.C. 103, the examiner must provide evidence which as a whole shows that the legal determination sought to be proved (i.e. the reference teachings establish a *prima facie* case of obviousness) is more probable than not."

The applicants present that the very fact that the rejections based on PI 9303217, Znaiden et al. and the 112, first paragraph have been withdrawn and reinstated (some more than once), that this is *prima facie* evidence that no preponderance of evidence exist whereby one of ordinary skill in the art could definitively state that it is more likely than not that the references render the applicants' claimed invention to be obvious.

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Closing

Applicants also believe that this application is in condition for allowance. However, should any issue(s) of a minor nature remain, the Examiner is respectfully requested to telephone the undersigned at telephone number (212) 808-0700 so that the issue(s) might be promptly resolved.

Respectfully submitted,

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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that the foregoing Amendment under 37 CFR § 1.111 (10 pages) is being facsimile transmitted to the United States Patent and Trademark Office on the date indicated below:

Date: 3 February 2004

By: Agata Glinska
Agata Glinska